

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vickie Forster  
Registration Specialist  
Regulatory Affairs - Biotechnology  
AgrEvo USA Company  
Little Falls Centre One  
2711 Centerville Road  
Wilmington, Delaware 19808

Dear Ms. Forster:

This letter is in regard to your genetically modified sugar beet line containing transformation event T120-7, about which you initiated consultation with the Agency in September of 1996. According to AgrEvo, the new sugar beet variety has been rendered tolerant to the herbicide glufosinate through the expression of the *pat* gene derived from *Streptomyces viridochromogenes*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment for the new sugar beet variety on June 19, 1998. These communications informed FDA of the steps taken by AgrEvo to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that the new sugar beet line is not materially different in composition, safety, or other relevant parameters from sugar beet varieties currently on the market, and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0038 and that will be maintained in the Office of Premarket Approval.

Based on the information AgrEvo has presented to FDA, we have no further questions concerning glufosinate-tolerant sugar beet containing transformation event T120-7 at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

cc: HFS-13 HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247 HFV-200 BNF 0038